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IS 13141 (1991): Neurosurgical Instruments-Leksell's Rongeur [MHD 7: Neurosurgery Instruments Implants and Accessories]

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तन्त्र शल्य क्रिया उपकरण — लैंकसेल, रौन्जर — विशिष्टि

Indian Standard

NEUROSURGICAL INSTRUMENTS-LEKSELL'S RONGEUR — SPECIFICATION

UDC 616·8-089-72 : 615·472·4

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Price Group 2

Neurosurgery Instruments Sectional Committee, MHD 7

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Neurosurgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard covers the dimensional and other requirements for Leksell's pattern, double action rongeur used in neurosurgery.

For the purpose of deciding whether a particular requirement of this standardis complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with **IS** 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

NBUROSURGICAL INSTRUMENTS- LEKSELL'S RONGBUR — SPECIFICATION

1 SCOPE

1.1 This standard specifies dimensional and other requirements for Leksell's pattern, double action rongeur used in neurosurgery.

2 REFERENCES

2.1 The following Indian Standards are necessary adjuncts to this standard:

IS No.	*Title*
6603 : 1972	Stainless steel bars and flats
7531 : 1990	Methods for testing of corrosion resistance of stainless steel surgical instruments (*first revision*)

3 SHAPE AND DIMENSIONS

3.2 The shape and dimensions of Leksell's rongeur shall be as shown in Fig. 1.

3.2 The diameter at the tip the rongeur shall be 4, 6 and 8 mm. The corresponding width at the cross section XX shall be 6, 8 and 10 mm.

3.3 Tolerances on various linear dimensions shall be as follows:

a) ±0·1 mm on dimensions up to 2·0 mm;

b) ±0·2 mm on dimensions above 2·0 mm and up to 5·0 mm;

c) ±1·0 mm on dimensions above 5·0 mm and up to 20·0 mm;

d) ±1·5 mm on dimensions above 20·0 mm and up to 50·0 mm; and

e) ±2·0 mm on dimensions above 50·0 mm.

4 MATERIAL

4.1 Jaws

Jaws shall be made of stainless steel conforming to Designation 40Cr13 of IS 6603 : 1972.

4.2 Arms and Springs

Arms and springs shall be made of stainless steel conforming to Designation 30Cr13 of IS 6603 : 1972.

4.3 Screws

Screw shall be made of stainless steel conforming to 20Cr13 of IS 6603 : 1972.

5 REQUIREMENTS

5.1 Workmanship

The rongeur shall be of symmetrical and balanced construction. The screws shall be well formed and shall have regular threads. The joints shall have no undue play and shall work smoothly. The spring action shall be smooth. It shall be neither too hard nor too slack. The compound action shall be smooth and free from jerks. The cutting edges shall be sharp, uniform and free from nicks. They shall match evenly when the jaws are closed. The arms of the rongeur shall be either matt finished on knurled. Grooves on the outer surface of the handle shall be shallow and gently rounded off, so that these do not hurt the fingers while in use.

5.2 Heat Treatment and Hardness

Various components of the rongeur shall be suitably hardened and tempered to give a hardness of:

a) 500 to 600 *HV* for jaws

b) 420 to 470 *HV* for arms and springs

c) 290 to 320 *HV* for screws

5.3 Surface Condition

All surfaces shall be free from pores, crevices and grinding marks. The rongeur shall be supplied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

5.4 Surface Finish

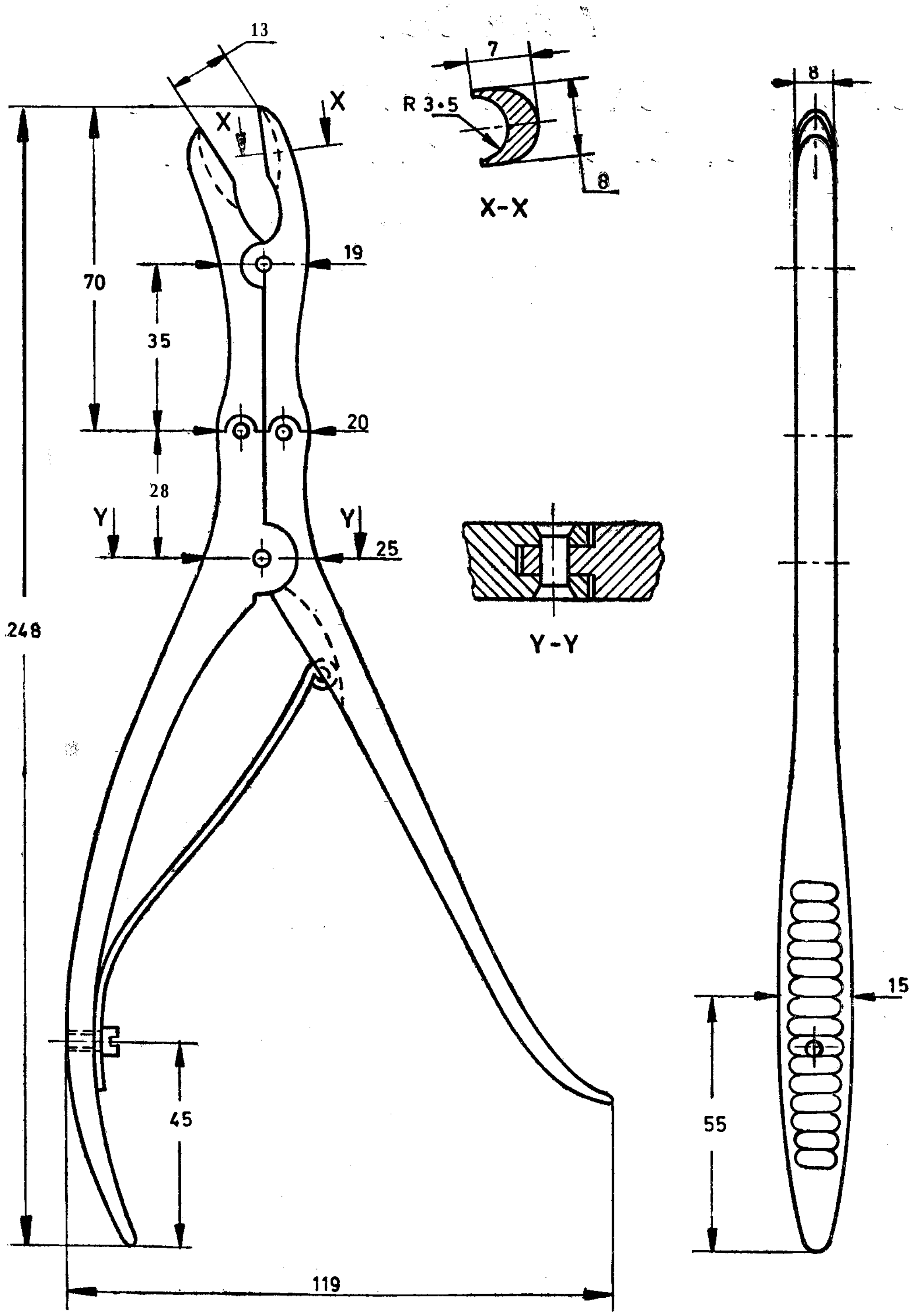
The surface finish shall be one of, or a combination of the following:

a) mirror polished;

b) reflection-reducing, for example satin finish, matt black finish.

NOTE — The satin finish should be effected by an appropriate procedure, such as grinding, brushing electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be affected by an appropriate procedure such as polishing, brushing, electropolishing, and mirror buffing.



All dimensions in millimetres.

FIG. 1 LEKSELL'S RONOEUR

5.5 Passivation and Final Treatment

The rongeur shall be treated by a suitable passivation process.

NOTES

1 Examples of methods of passivation are by electropolishing or by treating with 10 % (v/v) nitric acid solution for not less than 30 minutes at a temperature of not less than 10°C and not exceeding 60°C. The rongeur should then be rinsed in water and dried in hot air.

2 If the joints are lubricated, the lubricant should be non-corrosive and suitable for medical application according to Indian pharmacopoeia.

6 TESTS

6.1 Performance Test

Cut a piece of skull bone or teakwood of 3 mm to 4 mm thickness five times with the instrument. Each time it shall nibble clearly and with ease. On completion of the test, the cutting edges and the instrument as a whole shall not show any sign of damage.

6.2 Rigidity Test

A compressive force of 110 Newtons shall be applied to the rongeur arms at a distance of 75 mm from free ends in such a manner that it tends to press the arms together. The maximum force shall be attained gradually and shall act for two minutes. On completion of the test, the rongeur shall show no sign of damage.

6.3 Corrosion Resistance Test

The rongeur shall be subjected to boiling and autoclaving tests as prescribed in IS 7531 : 1990. The rongeur shall pass the tests.

7 MARKING

7.1 Each rongeur shall be suitably marked by etching or otherwise with the following:

a) indication of the source of manufacture; and

b) the words 'Stainless Steel' or letters 'S.S.'.

8 PACKING

8.1 Each rongeur may be wrapped in a moisture-proof paper or put in a polyethlyene bag and packed in cardboard cartons. The rongeur may also be packed as agreed to between the purchaser and the supplier.

Standard Mark

The use of the Standard Mark is governed by the provisions of the *Bureau of* Indian *Standards Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.